No. 95-1336

Supreme Court, U.S.
FILED
MAR 22 1996
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In The

# Supreme Court of the United States

October Term, 1995

ADA M. MARTIN and HAROLD L. MARTIN,

*Petitioners,*

*vs.*

TELECTRONICS PACING SYSTEMS, INC.; TPLC INC., doing business as Telectronics Pacing Systems; Telectronics PTY Limited,

*Respondents.*

*On Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit*

## RESPONDENTS' BRIEF IN OPPOSITION

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## RULE 29.6 STATEMENT

Respondents Telectronics Pacing Systems, Inc., TPLC, Inc., d/b/a Telectronics Pacing Systems, and Telectronics PTY Limited, are related corporations that are each beneficially owned by Pacific Dunlop Ltd. as the ultimate parent corporation. A list of all Pacific Dunlop Ltd. subsidiaries is submitted as a Lodging Appendix.

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## COUNTERSTATEMENT OF THE CASE

Respondents generally accept as accurate the Statement of the Case included in the Petition for Writ of Certiorari. Pursuant to Sup. Ct. R. 15.2, however, Respondents address the following perceived misstatement of fact included in Petitioners' brief.

Petitioners contend that on or after March 31, 1992, the Guardian 4210 Cardioverter/Defibrillator System manufactured and/or supplied by Respondents and implanted in Petitioner, Ada Martin, "began to malfunction . . . which required surgical replacement of the system on November 9, 1992." Pet. at 4. Petitioners made a similar claim in their Initial Brief submitted to the Sixth Circuit Court of Appeals, but conceded in their Reply Brief that "There is no doubt that this was not determined as 'fact'. . . ."

Respondents acknowledge the allegation in Petitioners' underlying complaint that the Guardian System malfunctioned. Respondents further acknowledge that at summary judgment — the stage of the proceedings in which this case was initially decided — all evidence and all reasonable inferences must be viewed in the light most favorable to the non-moving party. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970). This is not to say, however, that the favorable view accorded to Petitioners' allegations for purposes of summary judgment establishes as "fact" the matters included in those allegations. Accordingly, Respondents respectfully disagree with Petitioners' statement regarding the alleged malfunction of the Guardian System.

## REASONS FOR DENYING THE WRIT

### I.

### THIS CASE DOES NOT PRESENT A CONSTITUTIONAL ISSUE THAT SHOULD BE DECIDED BY THIS COURT [RESTATED].

The Constitution establishes our federal government as a government of limited powers, and carefully defines the areas in which federal authority may appropriately be exercised. Within those carefully defined areas, however, the "Supremacy Clause" of the Constitution provides that federal law "shall be the supreme Law of the Land . . . , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. This Court has held again and again that Congress has the authority under the Supremacy Clause to preempt state law, including state common law claims. *E.g., American Airlines, Inc. v. Wolens,* 115 S. Ct. 817 (1995); *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504 (1992); *Morales v. Trans World Airlines, Inc.,* 504 U.S. 374 (1992); *Chicago & N.W. Transportation Co. v. Kalo Brick & Tile Co.,* 450 U.S. 311 (1981); *Texas & Pacific Rwy. Co. v. Abilene Cotton Oil Co.,* 204 U.S. 426 (1907).

Notwithstanding this precedent, Petitioners submit that the Seventh Amendment constrains the supremacy of federal law to the extent it impacts upon any state common law claims that existed as of December 15, 1791, the date the Seventh Amendment was ratified. In other words, Petitioners assert that Congress is powerless to preempt traditional state common law claims even when Congress is appropriately exercising the authority given it under Article I of the Constitution.[1] This

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1. Petitioners have not suggested that federal regulation of medical devices, as embodied in the Medical Device Amendments to the Food, Drug and Cosmetic Act, is an inappropriate exercise of congressional power or that such regulation exceeds the limits established in Article I.

argument misapprehends the language, the scope and the very purpose of the Seventh Amendment and thus does not raise a constitutional issue worthy of review by this Court.

In its entirety, the Seventh Amendment provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of common law.

As the language of the amendment itself makes plain, the right being protected — the right to a jury trial in civil lawsuits — presupposes the existence of a "Suit[ ] at common law." In this case, there is no "Suit[ ] at common law" because Petitioners' common law claims have been expressly preempted, a priori, by the Medical Device Amendments to the federal Food, Drug and Cosmetic Act. Where there is no "Suit[ ] at common law" due to the operation of the Supremacy Clause, the right of trial by jury simply is not implicated because there is no underlying lawsuit to which the right can attach.

The Sixth Circuit Court of Appeals correctly stated this principle, observing that

> [n]othing in its text or history indicates that the Seventh Amendment protects the existence of certain common-law causes of action. . . . Here, as plaintiffs' causes of action have been preempted by federal law, they have no "suit[ ] at common law" and the Seventh Amendment's guarantees are not implicated.

*Martin v. Telectronics Pacing Systems, Inc.*, 70 F.3d 39, 42 (6th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3593 (U.S. Feb. 20, 1996) (No. 95-1336). This same reasoning is reflected in numerous court decisions holding that there is no constitutionally protected right to bring a tort claim.[2] The reasoning articulated by the Sixth Circuit Court of Appeals also comports with numerous analogous decisions involving the right of trial by jury. For example, in *Etalook v. Exxon Pipeline Co.*, 831 F.2d 1440 (9th Cir. 1987), the court addressed the question whether granting summary judgment infringes on a litigant's right to a jury trial. The court concluded that "no right of jury trial exists unless there is a genuine issue of material fact suitable for a jury to resolve." *Id.* at 1447. Similarly, in *3 Penny Theater Corp. v. Plitt Theatres, Inc.*, 812 F.2d 337 (7th Cir. 1987), the court concluded that dismissal of a plaintiff's claims with prejudice for failure to prosecute pursuant to Fed. R. Civ. P. 41(b) did not violate the plaintiff's right to a trial by jury. And in *Sullivan v. United States*, 788 F.2d 813 (1st Cir. 1986), the court found no violation of the plaintiff's right to a jury trial based on the trial court's dismissal for failure to state a claim upon which relief could be granted.

In each of the above-cited decisions, the right to trial by jury never arose because plaintiff's claims were determined to be unsupportable *as a matter of law*. Given the time-honored role of juries as finders of *fact*, there is no legal or logical reason for jury involvement in a case that can be and is decided on purely

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2. *See, e.g., Cooperativa de Ahorro y Credito Aguada v. Kidder, Peabody & Co.*, 993 F.2d 269 (1st Cir. 1993) (no protectable right in a tort claim "until a final, unreviewable judgment has been obtained") (citations omitted); *Hammond v. United States*, 786 F.2d 8 (1st Cir. 1986) (same); *Lamb ex rel. Donaldson v. Volkswagenwerk Aktiengesellschaft*, 631 F. Supp. 1144 (S.D. Fla. 1986) (no constitutionally protected right in a tort claim), *aff'd, Eddings ex rel. Eddings v. Volkswagenwerk, A.G.*, 835 F.2d 1369 (11th Cir.), *cert. denied, Griffin ex rel. Griffin v. Ford Motor Co.*, 488 U.S. 822 (1988).

legal grounds. It necessarily follows that claims which can be resolved as a matter of law simply do not implicate Seventh Amendment guarantees. This case is no different. Petitioners' claims were held to be preempted by the express preemption provisions of the MDA as a matter of law. As a result, the right to trial by jury never becomes an issue.

Petitioners' argument to the contrary turns this straightforward calculus on its head. According to Petitioners, it is not the right to jury trial that is preserved by the Seventh Amendment, but the underlying common law claim itself: "Congress cannot pass a law that abrogates an individual's right to a trial by jury where the cause of action existed prior to 1791; and the Seventh Amendment as an amendment takes precedence over the Supremacy Clause." Pet. at 12. Stretched to its extreme, this argument would make it impossible for a court to ever dispose of a lawsuit on purely legal grounds without running afoul of the Seventh Amendment. Similarly, this argument would make it impossible for Congress to exercise its power under Article I and the Supremacy Clause if, in so doing, it undermined any common law theory of recovery which may have existed in the late eighteenth century.

Indeed, careful consideration of Petitioners' argument reveals inherent contradictions and fatal flaws in logic. For instance, acceptance of Petitioners' argument would, at some fundamental level, result in the wholesale destruction of the common law paradigm. Instead of an evolving body of law representing the culmination of legal principles and societal wisdom gleaned through the ages, Petitioners' vision of the common law is one that is fixed in time. According to Petitioners, the Seventh Amendment essentially codified the common law as it existed in 1791 and admits of no alterations to that codification. Accepting Petitioners' argument, however, would be tantamount to accepting blanket prohibition of the

growth, change and adaptation that are the hallmarks of our common law system, and would effectively consign the contributions of such legal lights as Holmes, Cardozo and Llwellyn to the scrap heap. It is doubtful at best whether the Framers could have intended such a result while simultaneously embracing the common law heritage of their English forebears.

That this Court has traditionally taken an "historical approach" in its Seventh Amendment jurisprudence does not save Petitioners' argument. This Court has long interpreted the Seventh Amendment as reaching only those cases cognizable in law, as opposed to those historically brought in equity or admiralty. *See Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33 (1989). To make these distinctions in a manner consistent with the Framers' intent, this Court has found it is necessary to conduct an historical analysis of the differences among law, equity and admiralty as they existed in 1791. *E.g., Tull v. United States*, 481 U.S. 412 (1987). It is a leap of illogic, however, for Petitioners to draw from this analytical approach the conclusion that the Framers intended the Seventh Amendment to petrify the common law itself as it existed in eighteenth century America.

Petitioners candidly admit there is no authority whatsoever for the proposition that "the Seventh Amendment preserve[s] a cause of action in and of itself." Pet. at 11. Perhaps as a result of this dearth of supporting authority, Petitioners attempt to supplement their Seventh Amendment argument with one involving unspecified due process claims. Petitioners argue that "The touchstone of due process is the protection of the individual against arbitrary actions of government," and that if Congress preempts state tort law claims without providing a comparable federal remedy "it has acted . . . arbitrarily." Pet. at 11-12. Petitioners attempted this same gambit before the Sixth Circuit, presenting a Fifth Amendment due process argument for the first

time on appeal.[3] The Sixth Circuit declined to entertain Petitioners' due process argument because it had not been presented to the trial court and was therefore waived. *See Martin*, 70 F.3d at 41n.3. This Court should similarly decline Petitioners' invitation to read a due process component into their Seventh Amendment claim. *Shelley v. Kraemer*, 334 U.S. 1 (1948) (holding that constitutional arguments not pleaded or adequately raised or preserved in the trial court are waived on appeal).

In any event, even if Petitioners had properly raised and preserved their due process arguments they would present no important question of federal law that should be decided by this Court. Virtually the same due process argument has already been considered in the context of federal preemption under ERISA by the Seventh Circuit Court of Appeals in *Brown v. Retirement Committee of Briggs & Stratton Retirement Plan*, 797 F.2d 521 (7th Cir. 1986), *cert. denied*, 479 U.S. 1094 (1987). Rejecting the argument, the *Brown* Court cogently observed:

> [Plaintiff] apparently contends that Congress violated the fifth amendment by enacting ERISA which Brown alleges deprived her without due process of her Seventh Amendment right to a jury trial. Brown, however, received any process she was due through the legislative procedure used to enact ERISA. "When the legislature passes a law which affects a general class of

3. Petitioners also quote the Ninth and Tenth Amendments, apparently for the proposition that the Constitution does not grant Congress the authority to preempt state common law claims. Pet. at 7-8. As with Petitioners' due process argument, no reference was made to the Ninth and Tenth Amendments at trial as potential grounds for invalidating the MDA. Accordingly, these arguments should not now be considered for the first time on appeal.

> persons, those persons have all received procedural due process—the legislative process."

*Id.* at 527 (quoting J. Nowak, *et al.*, *Constitutional Law* 556 (1983)). The same reasoning applies with equal force in this case. Because Petitioners were afforded all due legislative process, there are no remaining issues for this Court to decide.

## II.

## THE DECISION BELOW DOES NOT CONFLICT WITH RELEVANT DECISIONS OF OTHER COURTS OF APPEAL AND INTERPRETS THE STATUTE, 28 U.S.C. § 360k(a), IN ACCORDANCE WITH CONGRESSIONAL INTENT [RESTATED].

When it enacted the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, Congress included the following express preemption provision:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Sixth Circuit Court of Appeals held that Petitioners' state law claims were expressly preempted under this provision of the MDA. In so doing, the appellate court aligned itself with the First, Second, Third, Fourth, Fifth, Seventh, Eighth and Eleventh Circuits, each of which has held that the MDA expressly preempts state law claims identical to those at issue here.

Petitioners assert, however, that the Sixth Circuit's decision, as well as those of the other courts referenced above, conflict with the decision of the Ninth Circuit in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995). In a general sense, Petitioners' statement is accurate: the *Kennedy* court held broadly that Congress did not intend to preempt state common law claims when it enacted the MDA, while the remaining circuit courts, following this Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), have uniformly held that the explicit language of the MDA's preemption provision reveals Congressional intent to preempt state common law as well as state legislation, regulation and administrative rules. As Petitioners' observe in their brief, this conflict among the circuits has been brought to this Court's attention in *Medtronic, Inc. v. Lohr*, No. 95-754 and *Lohr v. Medtronic, Inc.*, No. 95-886, *cert. granted*, 116 S. Ct. 806 (1996).[4]

In a more narrowly defined context, however, Respondents suggest there is no conflict among the circuits regarding the precise issues decided by the Sixth Circuit in this case. As Petitioners acknowledge, the medical device at issue here was authorized for limited market distribution pursuant to an Investigational Device Exemption ("IDE") issued by the Food

4. Both Petitioner and Cross-petitioners in *Medtronic, Inc. v. Lohr* point out the fundamental conflict created by the *Kennedy* decision. However, both Petitioner and Cross-petitioners devote substantially more attention to apparent conflicts among the circuits regarding the particular FDA requirements applicable to the device at issue in that case.

and Drug Administration ("FDA"). To date, every federal appellate court called upon to address the issue has agreed that the MDA preempts state common law claims in the context of IDE devices.[5] Respondents are aware of no post-*Cipollone* federal appellate decision holding to the contrary. Respondents therefore respectfully submit that there is no conflict among the circuits on the narrow issue presented here.

By contrast to the uniform judicial treatment of IDE devices, there has indeed been a fair amount of controversy over the preemption of claims related to medical devices that reach the market via other regulatory routes. For example, the device at issue in *Lohr* is known as a "510(k) device"[6] which the FDA authorized for market distribution under the MDA's Premarket Notification process. The Eleventh Circuit, while generally upholding the MDA's preemptive effect on state common law claims, held that design-related claims were not preempted because the Premarket Notification process did not impose design "requirements," and accordingly that design-related

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5. *See Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995) (holding that defective design, defective manufacture, failure to warn and failure to test claims against manufacturer of investigational intraocular lens were preempted); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.) (holding that product liability claims against manufacturer of investigational intraocular lens were preempted), *cert. denied*, 115 S. Ct. 429 (1994); *Hinners v. Optical Radiation Corp.*, No. 92-3148 (11th Cir. 1994) (unpublished per curiam opinion referenced at 15 F.3d 1096, "Table of Decisions Without Reported Opinions) (holding that negligence, breach of implied warranty and strict liability claims were preempted); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994) (per curiam) (holding that negligence, strict liability and breach of implied warranty claims were preempted); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992) (holding that inadequate testing, defective design and failure to warn claims were preempted).

6. Named after section 510(k) of the original MDA enactment, now codified at 21 U.S.C. 360(k).

claims would not result in the imposition of different or additional requirements prohibited by § 360k(a). This result is consistent with the Fifth Circuit's decision in *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), *petitions for cert. filed*, 64 U.S.L.W. 3469 (U.S. Dec. 26, 1995) (No. 95-1037) & 64 U.S.L.W. 3534 (U.S. Jan. 26, 1996) (No. 95-1214), but conflicts with the reasoning and result in *Duvall v. Bristol-Myers Squibb Co.*, 65 F.2d 392 (4th Cir.), *petition for cert. filed*, 64 U.S.L.W. 3439 (U.S. Dec. 22, 1995).

To further complicate matters, the device at issue in *Kennedy* was cleared for market distribution under the MDA's Premarket Approval ("PMA") process, a process which "involves the most rigorous review of devices under the [MDA]."[7] Given the comprehensive nature of the FDA regulations involved, every federal appellate court confronted with the issue, with the notable exception of the *Kennedy* court, has concluded that the MDA preempts state law claims against the manufacturer of PMA devices.[8] Adding to the controversy, although the majority of federal appellate courts are in general agreement as to the MDA's preemptive impact on claims related to PMA devices, there remain minor, specific differences in the scope and application of the MDA's preemption provision from circuit to circuit.[9]

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7. *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 384 n.2 (D.S.C. 1991).

8. *E.g., Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3593 (U.S. Feb. 20, 1996) (No. 95-1323); *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3593 (U.S. Feb. 16, 1996) (No. 95-1321); *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995); *Martello v. Ciba-Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993).

9. *Compare King*, 983 F.2d at 1135 (holding that express warranty claims related to PMA devices are preempted) *with Michael*, 46 F.3d at 326-27

(Cont'd)

It is apparent that the differences among federal regulation of IDE, PMA and 510(k) devices have been significant factors in the decisions of the various appellate courts. Respondents submit, however, that "preemption does not depend on the route the product takes to the market,"[10] and therefore acknowledge that the *Kennedy* decision may establish a direct conflict with the opinion of the Sixth Circuit in this case. Nevertheless, the Petition for Certiorari should be denied because, unlike the *Kennedy* decision, the Sixth Circuit's opinion is consistent with and carefully tracks the language of the MDA, the statute's legislative history, the FDA's implementing regulations, and the prior decisions of this Court.

As this Court has observed, "the purpose of Congress is the ultimate touchstone of preemption analysis." *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978). Moreover, as this Court has instructed time and again, the language included in the federal law itself provides the very best indicium of Congressional intent. *E.g., Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 571 (1982) ("There is, of course, nor more persuasive evidence of the purpose of a statute than the words by which the legislature undertook to give expression to its wishes.") (citations omitted); *Product Safety Comm'n v. GTE Sylvania*, 447 U.S. 102, 108 (1980) ("The starting point for interpretation of a statute is the language of the statute itself. Absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive.").

The intent of Congress could not have been more clearly expressed than in the language of the MDA. By its explicit terms, the MDA preempts "any requirement" imposed under color of

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(Cont'd)
(holding that express warranty claims related to PMA devices are not preempted).

10. *Feldt v. Mentor Corp.*, 61 F.3d 431, 434 (5th Cir. 1995).

state law that is "different from, or in addition to, any requirement applicable . . . to the device" and that "relates to" the device's safety, effectiveness, or any other matter "included in a requirement applicable to the device" under the MDA.

In *Cipollone*, this Court construed the term "requirement" in a similar preemption clause as one that "sweeps broadly and suggests no distinction between positive enactments and common law."[11] In *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374 (1992), the Court reiterated its well-settled view that the phrase "relates to" when used in an express preemption provision is indicative of "a broad pre-emptive purpose." The use of such broad and sweeping language in the preemption clause of the MDA firmly establishes Congressional intent to preempt the exact type of additional or different requirements that Petitioners would impose through their claims against Respondents under color of Ohio law. As this Court noted in *Cipollone*, " 'We must give effect to this plain language unless there is good reason to believe Congress intended the language to have some more restrictive meaning.' "[12]

A review of the legislative history accompanying consideration and passage of the MDA illustrates that Congress did not intend the language it chose to have some more restrictive

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11. *Id.* at 521. The *Kennedy* court all but disregards the reasoning in *Cipollone*, choosing instead to characterize state common law claims as exerting only "an indirect regulatory effect" on their targets. By contrast, this Court correctly and unequivocally observed that " '[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be a potent method of governing conduct and controlling policy.' " *Id.* (quoting *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)).

12. *Id.* (quoting *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983)).

meaning. For instance, in subcommittee hearings leading up to the bill's enactment, at least one Congressman urged passage of the MDA to replace the "piecemeal" and "after the fact" approach typified by then-existing judicial remedies.[13] Thus, contrary to the statement made in the initial brief submitted by Cross-petitioners in *Lohr* ("the legislative history mentions nothing about preemption of damages claims"), and the intimation in the *Kennedy* opinion that Congress had, "without comment," decided to displace traditional tort remedies, Congress was well aware of the ineffectiveness of the common law system it intended to replace with the comprehensive regulatory and remedial scheme embodied in the MDA.

Additionally, legislative history reveals that one of the fundamental goals of the MDA was to ensure that "innovations in medical device technology are not stifled by unnecessary restrictions."[14] Congressional intent on this point is particularly significant with respect to IDE devices. The investigational device program, specifically authorized by the MDA and carefully regulated by the FDA, exemplifies the Congressional goal of promoting "innovations in medical device technology." As the Seventh Circuit recognized in *Slater v. Optical Radiation Corp.*, the IDE process was "intended to encourage innovation by exempting promising experimental devices from the usual requirement" of proving safety and efficacy before a device is approved for widespread market distribution.[15] Moreover, the same court correctly reasoned that substantive standards for design, manufacturing and labeling imposed through state tort

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13. *See Hearings before the Subcommittee on Health & the Environment of the Committee on Interstate & Foreign Commerce on H.R. 5545, H.R. 974 & S. 510*, 94th Cong., 1st Sess. 201 (1975) (Statement of Rep. Fred Rooney).

14. H.R. Rep. No. 853, 94th Cong., 2d Sess. 9 (1976).

15. 961 F.2d at 1330, 1331-32 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992).

law claims would subvert this process and thus defeat one of the fundamental goals of the MDA.

The FDA's implementing regulations lend further support to the proposition that Congress intended the MDA's preemption provision to reach state common law claims. Specifically, the FDA interprets § 360k(a) as preempting "any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, *or court decision*)."[16] The suggestion by the *Kennedy* court that this reference applies solely to court decisions construing state statutes or regulations directed exclusively to medical devices is simply not supported in the language of the regulation itself. The better reading, and the only one consistent with this Court's *Cipollone* decision, is that the reference to court decisions means any court decision which would result in the imposition of an additional or different requirement on a device regulated under the MDA.

## CONCLUSION

For the foregoing reasons, Respondents pray that this Court deny the Petition for Writ of Certiorari sought by Petitioners, thus maintaining intact the considered opinion of the Sixth Circuit Court of Appeals.

Should this Court determine, however, that Petitioners' request has merit, Respondents respectfully suggest that the Court consider consolidating this case, and perhaps *Mitchell v. Collagen Corp.* as well, with the pending appeal in *Medtronic, Inc. v. Lohr.* Respondents suggest this approach as a means of allowing this Court to consider and resolve in one proceeding the question of preemption under the MDA regardless of whether a

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16. 21 C.F.R. § 808.1(b) (emphasis added).

particular device came to market through the IDE, PMA or 510(k) process.

Respondents are mindful of the fact that the *Lohr* appeal has been scheduled for briefing and argument this term, and that consolidation would delay resolution. In the alternative, then, Respondents would respectfully request that the Court hold the Petition in this case pending the outcome of the *Lohr* appeal, and reexamine at that point whether there are any remaining issues specific to IDE devices that remain unresolved.

Respectfully submitted

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